

### REMARKS

Claims 1 and 3-6 are pending in this application. By this Amendment, Claims 1 and 4 are amended and Claim 6 is added. Because support for the claim amendments is provided in the originally filed application, such as, for example, page 6, lines 11-13 and Figure 3, Applicant respectfully submits that no new matter is presented herein.

#### Claim Rejection – 35 U.S.C. § 112

Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended the claim in a manner believed to be responsive to the rejection.

Applicant respectfully requests withdrawal of the rejection.

#### Claim Rejection – 35 U.S.C. § 102

Claims 1 and 2-5 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,450,163 to Blacker et al. Applicant respectfully traverses the rejection for the following reason(s).

Claim 1, as amended, recites an apparatus for nebulising a liquid, in particular for aerosol therapy, the apparatus, including, among other features, a nebulising ampoule and a valve for regulating a flow of air into and/or out of the ampoule, the valve including, among other features, a shutter, ring and plurality of deformable elements, wherein ***the shutter, the ring and the deformable elements are integrally provided in and define a single body of the valve and wherein the single body is made of a polymeric material.*** Applicant respectfully notes that Figure 3 of the originally filed

application presents an exemplary embodiment of the claimed invention and in particular, the claimed features discussed above.

Applicant respectfully submits that the claimed invention relates to an apparatus for aerosol therapy having a valve that is able to operate immediately, i.e., a valve that can be opened and closed in very short time intervals. The problem to be solved by the present invention is to provide a valve that is easy to manufacture and easy to install on an ampoule.

Applicant further submits that the claimed valve is able to oppose a minimum resistance to opening and closing during the inspiration and expiration stages of use by an operator.

The Blacker apparatus includes a valve 60 that is defined by a plurality of mechanically interconnected elements. In particular, Applicant notes that the valve 60 includes a plunger like shutter 62 having a diverter 74 formed at a lower end thereof and which is slidably fit into the diverter guide 50 defined in the open upper end of a spring support member or ring 52. A spring or deformable element 84 sits on top of the ring 52 and around the body 68 of the shutter 62.

By virtue of the mechanical connection of the shutter 62, ring 52 and spring 84 components of the Blacker valve 60, Applicant respectfully submits that the shutter 62, ring 52 and spring 84 are not integrally provided in and define a body of the valve 60. Rather, the shutter 62, ring 52 and spring 84 are separate and distinct components that must first be manufactured separately and then assemble to define the valve 60. Such a valve 60 is not easy to assemble and requires multiple manufacturing and assembly

steps relative to the claimed invention, wherein the valve is manufactured in a single body.

Also, the metallic spring 84 controlling the opening/closing of the shutter 62 is not able to oppose a minimum resistance to opening/closing during the inspiration and expiration stages of use by an operator.

Put simply, the Blacker apparatus does not disclose, teach or otherwise suggest each and every feature recited by Claim 1.

To qualify as prior art under 35 U.S.C. §102, a single reference must teach, i.e., identically describe each and every feature recited by the rejected claim. Since Blacker fails to disclose or suggest each and every feature recited by Claim 1, Applicant submits Claim 1 is not anticipated by, or rendered obvious in view of Blacker and should be deemed allowable over the reference.

Claims 3-6 depend from Claim 1. It is respectfully submitted that these dependent claims be deemed allowable over Blacker for at least the same reasons Claim 1 is allowable as well as for the additional features recited therein.

Applicant respectfully requests withdrawal of the rejection.

### **Conclusion**

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of Claims 1 and 3-6, and the prompt issuance of a Notice of Allowability are respectfully solicited.

Should the Examiner believe anything further is desirable in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to counsel's Deposit Account No. 01-2300, **referencing docket number 024931.00026.**

Respectfully submitted,  
**ARENT FOX LLP**

A handwritten signature in black ink, appearing to read 'Murat Ozgu', is written over the printed name.

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Enclosure: Petition for Extension of Time (2 months)

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